

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Steven K. Burke.

Application No.: 10/686,808

Group: 1618

Filed: October 16, 2002

Examiner: Leah H. Schlientz

Confirmation No.: 8791

For: METHOD FOR PROMOTING BONE FORMATION

CERTIFICATE OF MAILING OR TRANSMISSION	
I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, or is being facsimile transmitted to the United States Patent and Trademark Office on:	
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Date	Signature
<u>Loyce D. Lange</u>	
Typed or printed name of person signing certificate	

DECLARATION OF MELISSA PLONE UNDER 37 C.F.R. 1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, Melissa Plone of Framingham, MA, declare and state that:

1. I am currently employed by Genzyme Corporation, 500 Kendall Street, Cambridge, MA 02142, where I serve as Data Analyst. Prior to my employment with Genzyme Corporation, I had been employed by Geltex Pharmaceuticals, 153 Second Avenue, Waltham, MA 02451, which merged with Genzyme Corporation effective April 1, 2003. I am generally familiar with the subject matter described in U.S. Serial No. 10/686,808 assigned to Genzyme Corporation, which currently claims methods for promoting bone formation and treatments for osteoporosis.

2. The responsibilities of my position at Genzyme Corporation, and previously at Geltex Pharmaceuticals, include managing clinical studies in which patients were administered

sevelamer hydrochloride, including studies evaluating the treatment of hyperphosphatemia in patients with end stage renal disease receiving hemodialysis. In addition, my responsibilities also include analyzing and reporting selected clinical data generated by these studies.

3. Prior to October 22, 2001 about nineteen clinical studies were conducted by Geltex Pharmaceuticals or Genzyme Corporation with sevelamer hydrochloride to investigate the safety and efficacy of sevelamer hydrochloride, particularly in the treatment of hyperphosphatemia. In one such study, osteocalcin, bone-specific alkaline phosphatase (BSAP), and c-telopeptides were measured in the study subjects. Trabecular and cortical bone density were calculated from Electron Beam Tomography (EBT) scans taken of the study participants during the course of the study. This study is reported as Example 1 on pages 17-20 of the pending patent application.

4. Between 14 and 2103 patients participated in each of the clinical studies described in Section 3. Some of these patients may have received a placebo treatment or an active control treatment which did not contain sevelamer hydrochloride. The length of these studies ranged from about one day to about twelve months.

5. I hereby acknowledge that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Melissa Plone

Melissa Plone

November 7, 2006

Date